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Filed : January 26, 2004

REMARKS

The foregoing amendments and the following remarks are responsive to the June 5, 2008 Final Office Action. Claims 1, 3, 5, 11, 15, and 16 are amended, Claims 2, 8, and 14 are cancelled without prejudice, Claims 4, 7, 12, 17, and 18 remain as previously presented, Claims 6, 13, 19, and 20 remain as originally filed, Claims 9, 10, and 21-23 were previously cancelled without prejudice, and Claims 24-31 are new. Thus, Claims 1, 3-7, 11-13, 15-20, and 24-31 are presented for further consideration. Please enter the amendments and reconsider the claims in view of the following remarks.

Comments on “Response to Amendment”

In the June 5, 2008 Final Office Action, in a section entitled “Response to Amendment,” the Examiner states that the “Declaration of Luis De Taboada Pursuant to 37 C.F.R. § 1.132” (“the Declaration”) filed October 30, 2007 was insufficient to overcome the rejection of claims in the previous office action because the Declaration “provides an opinion based on calculations regarding light penetration” and “[t]he Oron patent discloses light source intensity consistent with that of the Applicant that yields the claimed penetration.”

Applicants respectfully traverse the reasoning in the “Response to Amendment.” Applicants submit that the Declaration included objective evidence of unexpected results from the claimed invention. In particular, the Declaration provided evidence of brain tissue transmission coefficients that would have been expected by persons skilled in the art upon review of the available literature on the optical properties of brain tissue and factual evidence of measurements of the transmission of light through a cadaver human skull and brain. In view of such objective evidence, the patentability of the claimed invention is supposed to be reconsidered by weighing the objective evidence against any evidence supporting the rejection. *See*, M.P.E.P. § 716.01(d). Applicants submit that the “Response to Amendment” section of the June 5, 2008 Final Office Action does not indicate that such reconsideration by weighing the objective evidence of the Declaration has been performed.

To the extent that the Declaration also included opinion evidence, Applicants submit that M.P.E.P. § 716.01(c)(III) instructs that such opinion evidence is:

entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive.

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Therefore, even if the Declaration included opinion evidence in addition to the objective evidence, all the evidence of the Declaration should have been considered by the Examiner.

Contrary to the statement that the Oron patent discloses light source intensities consistent with that of the claimed invention, Applicants submit that the light intensities disclosed by Oron do not yield noninvasively delivering a power density of “at least about 0.01 mW/cm² at a depth of approximately 2 centimeters below the dura,” as recited by Claim 1. Oron discloses (i) applying light through an incision in the scalp of a rat (*i.e.*, invasively) so that a power density of 8 mW/cm² reaches the rat brain tissue; (ii) applying light through the skin and scalp of a mouse so that a power density of 5 mW/cm² reaches the mouse brain tissue; and (iii) applying light through a human skull so that a power density of 3 mW/cm² reaches the inner skull wall. As evidenced by the facts detailed in the Declaration, none of these disclosures by Oron equates to noninvasively delivering a power density of “at least about 0.01 mW/cm² at a depth of approximately 2 centimeters below the dura,” as recited by Claim 1.

For the foregoing reasons, Applicants respectfully traverse the reasoning in the “Response to Amendment.” Applicants reassert the remarks presented in the “Amendment and Response to May 31, 2007 Office Action” based on the Declaration, and these remarks as well as the Declaration are incorporated in their entirety by reference herein.

Response to Rejection of Claims 1-8 and 11-20 Under 35 U.S.C. § 102(b)

In the June 5, 2008 Final Office Action, the Examiner maintains the rejection of Claims 1-8 and 11-20 under 35 U.S.C. § 102(b) as being anticipated by PCT Publication No. WO99/62599 of Oron (“Oron”).

Applicants have cancelled Claims 2, 8, and 14 without prejudice, reserving the right to pursue allowance of these claims through continuation practice.

Claim 1

Applicants have amended Claim 1 to recite (emphasis added):

1. A method for enhancing neurologic function in a subject, said method comprising

providing a subject having a loss of neurologic function due to Parkinson’s disease or Alzheimer’s disease; and

noninvasively delivering a neurologic function enhancing effective amount of light energy having a wavelength in the visible to near-infrared wavelength range and a predetermined power density to the brain of the subject, wherein noninvasively delivering the neurologic function enhancing effective amount of light energy comprises

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transmitting light energy through the scalp and the skull to the brain, wherein the predetermined power density is at least about 0.01 mW/cm^2 at a depth of approximately 2 centimeters below the dura.

Applicants submit that amended Claim 1 includes features not disclosed or suggested by Oron. For example, Oron does not disclose or suggest “providing a subject having a loss of neurologic function due to Parkinson’s disease or Alzheimer’s disease,” and “noninvasively delivering a neurologic function enhancing effective amount of light energy,” as recited by amended Claim 1. Oron only discloses using laser irradiation to treat or protect cells under acute ischemic conditions in the brain (*see, e.g.*, Oron at page 3, lines 6-7) or hypoxia in newborns (*see, e.g.*, Oron at page 5, line 23 – page 6, line 7). In addition, the power densities disclosed by Oron are outside the range of the method recited by Claim 1. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Oron. Applicants respectfully request the Examiner withdraw the rejection and pass Claim 1 to allowance.

Claims 3-7 and 11-15

Each of Claims 3-7, 11-13, and 15 depends either directly or indirectly from amended Claim 1, and each of Claims 3-7, 11-13, and 15 includes additional features of particular utility. Therefore, for at least the reasons stated above with regard to amended Claim 1, Applicants submit that Claims 3-7, 11-13, and 15 are patentably distinguished over Oron. Applicants respectfully request that the Examiner withdraw the rejection and pass Claims 3-7, 11-13, and 15 to allowance.

Claim 16

Applicants have amended Claim 16 to recite (emphasis added):

16. A method of increasing neurologic function by increasing the production of ATP by neurons, comprising:

noninvasively irradiating neurons of a subject having a loss of neurologic function due to Parkinson’s disease or Alzheimer’s disease with light energy having a wavelength in the near infrared to visible portion of the electromagnetic spectrum for at least about 1 second;

wherein the power density of said light energy at the neurons is at least about 0.01 mW/cm^2 at a depth of approximately 2 centimeters below the dura, whereby the ATP production of neurons is increased.

Applicants submit that amended Claim 16 includes features not disclosed or suggested by Oron. For example, for at least reasons similar to those discussed above with regard to Claim 1, Oron does not disclose or suggest “noninvasively irradiating neurons of a subject having a loss of

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neurologic function due to Parkinson's disease or Alzheimer's disease with light energy," as recited by amended Claim 16. In addition, the power densities disclosed by Oron are outside the range of the method recited by Claim 16. Therefore, Applicants submit that amended Claim 16 is patentably distinguished over Oron. Applicants respectfully request the Examiner withdraw the rejection and pass Claim 16 to allowance.

Claims 17-20

Each of Claims 17-20 depends either directly or indirectly from amended Claim 16, and each of Claims 17-20 includes additional features of particular utility. Therefore, for at least the reasons stated above with regard to amended Claim 16, Applicants submit that Claims 17-20 are patentably distinguished over Oron. Applicants respectfully request the Examiner withdraw the rejection and pass Claims 17-20 to allowance.

Comments on Inherency

In the June 5, 2008 Final Office Action, the Examiner states that "[w]here a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, ... the reference meets the claim under the doctrine of inherency." Applicants respectfully traverse the implication that the disclosure of Oron necessarily results in the claimed invention. As described above with regard to the "Response to Amendments" section of the June 5, 2008 Final Office Action, Applicants submit that none of the Oron disclosure necessarily achieves the claimed invention. For example, disclosure (i) cited above is done invasively and each of disclosures (i), (ii), and (iii) are performed at power densities too small to achieve the power densities of the claimed invention. In addition, Oron does not disclose sufficient details regarding the laser spot size, beam profile, or beam divergence to determine whether the cited power densities at the brain surface would necessarily result in a power density of "at least about 0.01 mW/cm² at a depth of approximately 2 centimeters below the dura."

Pursuant to M.P.E.P. § 2112(IV), "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic" (emphasis in original; citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. "Inherency may not be established by probabilities or possibilities." *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999). To establish

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inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original).

Therefore, Applicants submit that the claimed invention is not inherent in the disclosure by Oron. Applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 3-7, 11-13, 15-20, and 24-31 and pass these claims to allowance.

Comments on New Claims 24-31

Applicants have added new Claims 24-31. Applicants submit that these new claims are supported by the application as originally filed, including but not limited to, paragraphs [0009]-[0061]. In particular, Claims 29-31 are supported by the application as originally filed, including but not limited to, paragraph [0045]. Applicants submit that new Claims 24-31 are in condition for allowance and respectfully requests such action.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Atty Docket No.	Title	Filed
11/766,037	ACULSR.050C1	Method of Treating or Preventing Depression	June 20, 2007

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11/482,220	ACULSR.005CP1C1	Device and Method for Providing Phototherapy to the Brain	July 7, 2006
10/938,423	ACULSR.5CP1CP2	Device and Method for Providing Phototherapy to the Brain	September 10, 2004
11/844,205	ACULSR.055A	Low Level Light Therapy For Enhancement of Neurologic Function of a Patient Affected by Parkinson's Disease	August 23, 2007

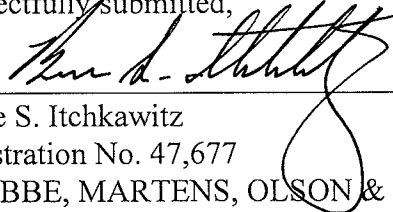
Summary

For at least the foregoing reasons, Applicants submit that Claims 1, 3-7, 11-13, 15-20, and 24-31 are in condition for allowance, and Applicants respectfully request such action.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

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Respectfully submitted,

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